



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3416-PN]

### Medicare and Medicaid Programs; Application from the American Association for Accreditation of Ambulatory Surgery Facilities for Continued Approval of its Rural Health Clinic (RHC) Accreditation Program

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for continued recognition as a national accrediting organization for rural health clinics (RHCs) that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's complete application, the Centers for Medicare and Medicaid Services (CMS) publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLIC INSPECTION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** In commenting, please refer to file code CMS-3416-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to

<http://www.regulations.gov>.

Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-3416-PN,  
P.O. Box 8016,  
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-3416-PN,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:**

Shonte Carter, (410) 786-3532.

Lillian Williams, (410) 786-8636.

**SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been

received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

## **I. Background**

Under the Medicare program, eligible beneficiaries may receive covered services from a rural health clinic (RHC), provided certain requirements are met. Sections 1861(aa) of the Social Security Act (the Act) establish distinct criteria for an entity seeking designation as an RHC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities and other entities are at 42 CFR part 488. The regulations at 42 CFR part 491, subpart A, specify the minimum conditions that an RHC must meet to participate in the Medicare program.

Generally, to enter into a provider agreement with the Medicare program, an RHC must first be certified by a state survey agency as complying with the conditions or requirements set forth in 42 CFR part 491, subpart A of our Medicare regulations. Thereafter, the RHC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

However, there is an alternative to surveys by state agencies. Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any

provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for CMS approval of their accreditation program under 42 CFR part 488, subpart A must provide CMS with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5. The regulations at § 488.5(e)(2)(i) require accrediting organizations to reapply for continued approval of their accreditation program every 6 years or sooner as determined by CMS.

The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF's) term of approval for their RHC accreditation program expires March 23, 2022.

## **II. Approval of Deeming Organizations**

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of AAAASF's request for continued approval for its RHC accreditation program. This notice also solicits public comment on whether AAAASF's requirements meet or exceed the Medicare conditions of participation

(CoPs) for RHCs.

### **III. Evaluation of Deeming Authority Request**

AAAASF submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its RHC accreditation program. This application was determined to be complete on August 25, 2021. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of AAAASF will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAAASF's standards for RHCs as compared with CMS' RHC CoPs.

- AAAASF's survey process to determine the following:

- ++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

- ++ The comparability of AAAASF's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited RHCs.

- ++ AAAASF's processes and procedures for monitoring RHCs found out of compliance with AAAASF's program requirements. These monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.9(c).

- ++ AAAASF's capacity to report deficiencies to the surveyed RHCs and respond to the RHC's plan of correction in a timely manner.

- ++ AAAASF's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ The adequacy of AAAASF's staff and other resources, and its financial viability.

- ++ AAAASF's capacity to adequately fund required surveys.

++ AAAASF's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ AAAASF's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ AAAASF's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

#### **IV. Collection of Information Requirements**

This document does not impose information collection requirements, that is reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

#### **V. Response to Comments**

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this notice. Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the Federal Register summarizing our response to comments and announcing the result of our evaluation.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: October 12, 2021.

**Lynette Wilson,**

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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